Summary of Safety and Effectiveness Data

I. GENERAL INFORMATION

Device Generic Name:	Permanent pacing electrode
Device Trade Name:	Stelid II endocardial pacing leads: Bipolar, ventricular leads - Models BTF25D & BTF26D, Unipolar ventricular leads - Models UTF25D & UTF26D, and Bipolar atrial leads -BJF24D & BJF25D Stelix endocardial pacing leads: Bipolar atrial leads - Models BR45D & BR46D Stelix II endocardial pacing leads: Bipolar atrial leads - Models BRF25D & BRF26D
Applicant's Name and Address:	ELA Medical, Inc. 2950 Xenium Lane North, Suite 120 Plymouth, MN 55441
Pre-Market Approval (PMA) Application Number:	P020030
Date of Panel Meeting:	Not Applicable
Date of Notice of Approval to the Applicant:	June 17, 2004

II. INDICATIONS FOR USE

The Stelid II, Stelix, and Stelix II steroid eluting endocardial pacing leads are designed to be used with an implantable pacemaker for pacing and sensing of the heart. The Stelid II models BTF25D/26D and UTF25D/26D are intended for permanent pacing and sensing of the ventricle. The Stelid II models BJF24D/25D, Stelix models BR45D/46D, and Stelix II models BRF25D/26D are intended for permanent pacing and sensing of the atrium.

III. CONTRAINDICATIONS

Implantation of endocardial leads is generally contraindicated in patients with mechanical tricuspid valves.

Do not implant in patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated.

IV. WARNINGS AND PRECAUTIONS

The Warnings and Precautions can be found in the Stelid II, Stelix, and Stelix II labeling.

V. DEVICE DESCRIPTION

The Stelid II BTF25D/26D leads are steroid eluting, tined, bipolar transvenous leads that provide a permanent electrical pathway between a pacemaker and the ventricle. The leads use a 2 mm^2 vitreous carbon tip electrode with a passive fixation mechanism. The proximal electrode is made of a platinum-iridium alloy. The BTF25D/26D leads are insulated with silicone rubber and have a silicone molded steroid collar that contains less than 1.0 mg of dexamethasone sodium phosphate.

The Stelid II UTF25D/26D leads are steroid eluting, tined unipolar transvenous leads that provide a permanent electrical pathway between a pacemaker and the ventricle. These leads are exactly the same as the Stelid II BTF25D/26D except for polarity and lead body diameter. The UTF25D/26D leads have a vitreous carbon tip electrode with a passive fixation mechanism, but they do not have a proximal electrode. The UTF25D/26D leads have a silicone molded steroid collar that contains less than 1.0 mg of dexamethasone sodium phosphate.

The Stelid II BJF24D/25D leads are steroid eluting, tined, bipolar transvenous leads that provide a permanent electrical pathway between a pacemaker and the atrium. These leads are exactly the same as the Stelid II BTF25D/26D except for their length, intended chamber of the heart and J shape.

The Stelix BR45D/46D leads are steroid eluting, retractable-screw, bipolar transvenous leads that provide a permanent electrical pathway between a pacemaker and the atrium. These leads are equipped with an active fixation device made of an extendable/retractable helix. The helix and proximal electrode are made of a platinum-iridium alloy. The BR45D/46D have a 4 mm^2 vitreous carbon tip electrode and a silicone molded collar that contains less than 1.0 mg of dexamethasone sodium phosphate.

The Stelix II BRF25D/26D leads are steroid eluting, retractable-screw, bipolar transvenous leads that provide a permanent electrical pathway between a pacemaker and the atrium. These leads are exactly the same as the Stelix BR45D/46D leads except that they use a 2 mm^2 vitreous carbon electrode. The BRF25D/26D leads have a silicone molded steroid collar that contains less than 1.0 mg of dexamethasone sodium phosphate.

All of the Stelid II, Stelix, and Stelix II models have IS-1 connectors.

The table below describes the technical specifications related to the lead models discussed in this document.

	Stelid II BTF25D/26D	**Stelid II UTF25D/26D**	**Stelid II BJF24D/25D**	**Stelix BR45D/46D**	**Stelix II BRF25D/26D**
Chamber	Ventricle	Ventricle	Atrium	Atrium	Atrium
Lead shape	Straight	Straight	J-shaped	Straight	Straight
Length	52/59 cm	52/59 cm	45/52	52/59 cm	52/59 cm
Electrode material	Vitreous carbon	Vitreous carbon	Vitreous carbon	Vitreous carbon	Vitreous carbon
Electrode size	2 mm^2	2 mm^2	2 mm^2	4 mm^2	2 mm^2
Steroid	<1.0 mg of dexamethasone sodium phosphate	<1.0 mg of dexamethasone sodium phosphate	<1.0 mg of dexamethasone sodium phosphate	<1.0 mg of dexamethasone sodium phosphate	<1.0 mg of dexamethasone sodium phosphate
Fixation	Four silicone tines	Four silicone tines	Four silicone tines	Retractable helix	Retractable helix
Body diameter	2 mm	1.6 mm	2.5 mm	2.5 mm	2.5 mm
Introducer size	8 F (2.66 mm)	8 F (2.66 mm)	8 F (2.66 mm)	9 F (3.33 mm)	9 F (3.33 mm)
Connector	IS-1 bipolar	IS-1 unipolar	IS-1 bipolar	IS-1 bipolar	IS-1 bipolar
Stylets furnished with lead	4 straight	4 straight	4 straight	2 straight 2 j-shaped 2 flat tip	2 straight 2 j-shaped 2 flat tip
Max pacing impedance	1000 Ω	1000 Ω	1000 Ω	900 Ω	1000 Ω
Max sensing impedance	1000 Ω	1000 Ω	1000 Ω	900 Ω	1000 Ω

The following ligature sleeves and stylets, packaged with the leads, are also available as separately packaged accessories:

- Ligature sleeve models XRL-430, XRL-432, and XRL-433
- Straight stylet models XRL-436, XRL-441, and XRL-446
- Flat tip yellow stylet models XRL-434 and XRL-435
- J-shaped stylet models XRL-437 and XRL-445

VI. ALTERNATIVE PRACTICES AND PROCEDURES

Surgery or drug therapy may be alternatives to cardiac pacing in certain instances, however, cardiac pacing is often the standard treatment for cardiac rhythm management. Endocardial pacing leads are an accepted means of providing a permanent electrical pathway between an implantable pacemaker and the heart. Other commercially available leads may meet the needs of patients requiring an implantable pulse generator.

VII. MARKETING HISTORY

The Stelix / Stelid devices are currently available for commercial distribution in the European Economic Area, Russia, Ukraine, Estonia, Saudi Arabia, Lebanon, China, India, Israel, Japan, Australia, New Zealand, Canada, Uruguay, and Argentina. No devices have been withdrawn from the market in any country for any reason related to safety or effectiveness.

VIII. ADVERSE EVENTS

Potential Adverse Events

Based on the literature and lead implant experience, the possible physical effects from implantation of a Stelid II, Stelix, or Stelix II lead are listed below in alphabetical order:

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac perforation / tamponade
- Chronic nerve damage
- Death
- Elevated pacing thresholds
- Erosion / extrusion
- Excessive fibrotic tissue growth
- Formation of hematomas or cysts
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Keloid formation
- Lead abrasion
- Lead displacement / dislodgment
- Lead fracture, insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Myocardial injury
- Myocardial irritability
- Oversensing / undersensing
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with external paddles
- Threshold elevation
- Thrombosis / thromboemboli

Observed Adverse Events

Three separate clinical studies were performed on the leads. The adverse events from each one are listed separately.

Stelid II BTF25D/26D steroid eluting ventricular leads and Stelix BR45D/46D steroid eluting atrial leads

A randomized controlled study was performed to assess the safety and effectiveness of the Stelid II and Stelix leads. There were 218 patients implanted with Stelix atrial leads and 224 patients implanted with Stelid II ventricular leads. The Stelix atrial leads are steroid eluting, retractable screw, bipolar leads and the Stelid II ventricular leads are also steroid eluting and use a $2mm^2$ vitreous carbon tip electrode with a passive fixation

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method. The choice of these lead models for the randomized controlled study allowed evaluation of both atrial and ventricular steroid eluting leads and both passive and active fixation. Patients were evaluated at pre-implant, implant, two weeks, one month, and three months post implant.

Table 1 summarizes the adverse events observed with the atrial leads and Table 2 summarizes the adverse events reported with the ventricular leads. The study investigator determined that no deaths were device related.

Table 1: Atrial lead adverse events (Stelix BR45D/46D)

	Stelix atrial lead				Control lead+			
Nature of event	Number of patients	Percent of patients	Number of events	Events per device year	Number of patients	Percent of patients	Number of events	Events per device year
Non-device related death	20	9.2 %	20	0.11	12	15.6 %	12	0.205
Dislodgement	4	1.8 %	4	0.02	1	1.3 %	1	0.017
Increased atrial pacing threshold and dislodgement	1	0.5 %	1	0.006	--	--	--	--
Loss of capture	--	--	--	--	2	2.6 %	2	0.034
Extracardiac stimulation	1	0.5 %	1	0.006	--	--	--	--
Pulmonary embolism	1	0.5 %	1	0.006	--	--	--	--
Undersensing/loss of sensing	3	1.4 %	3	0.017	--	--	--	--
Oversensing	--	--		--	2	2.6 %	2	0.034
Hematoma of the pocket and pocket infection	1	0.5 %	1	*	--	--	--	--
Leads reversed in the header	2	2.6 %	2	*	--	--	--	--
Pleural effusion	1	0.5 %	1	*	--	--	--	--
Pneumothorax	1	0.5 %	1	*	1	1.3 %	1	*
Pocket infection	2	2.6 %	2	*	--	--	--	--
Loss of slack in leads	1	0.5 %	1	*	--	--	--	--
Accumulation of fluid	1	0.5 %	1	*	--	--	--	--
Hematoma of the pocket	3	1.4 %	3	*	1	1.3 %	1	*
Transient edema of left arm	1	0.5 %	1	0.006	--	--	--	--
Serious, not related	55	25.2 %	82	0.3	25	32.5 %	52	0.44

* Events are related to the implant procedure and involve both atrial and ventricular leads. Therefore, calculation of the number of events per device year is not appropriate.

+ Commercially available leads

Table 2: Ventricular lead adverse events (Stelid II BTF 25D/26D)

Nature of event	Stelid II ventricular lead				Control lead+			
	Number of patients	Percent of patients	Number of events	Events per device year	Number of patients	Percent of patients	Number of events	Events per device year
Non-device related death	21	9.4 %	21	0.11	12	15.6 %	12	0.21
Dislodgement	3	1.4 %	3	0.016	--	--	--	--
Extracardiac stimulation	2	0.9 %	2	0.011	--	--	--	--
Loss of capture	1	0.4 %	1	0.005	--	--	--	--
Pulmonary embolism	1	0.4 %	1	0.005	--	--	--	--
Undersensing/loss of sensing	1	0.4 %	1	0.005	--	--	--	--
High ventricular pacing threshold	1	0.4 %	1	0.005	1	1.3 %	1	0.017
Oversensing and undersensing/loss of sensing	--	--	--	--	1	1.3 %	1	0.017
Hematoma of the pocket and pocket infection	1	0.5 %	1	*	--	--	--	--
Leads reversed in the header	2	2.6 %	2	*	--	--	--	--
Pleural effusion	1	0.5 %	2	*	--	--	--	--
Pneumothorax	1	0.5 %	1	*	1	1.3 %	1	*
Pocket infection	2	0.5 %	2	*	--	--	--	--
Loss of slack in leads	1	0.5 %	1	*	--	--	--	--
Accumulation of fluid	1	0.5 %	1	*	--	--	--	--
Hematoma of the pocket	3	1.4 %	3	*	1	1.3 %	1	*
Transient edema of left arm	1	0.5 %	1	*	--	--	--	--
Serious, not related	56	25.0 %	83	0.44	25	32.5 %	52	0.44

* Events are related to the implant procedure and involve both atrial and ventricular leads. Therefore, calculation of the number of events per device year is not appropriate.

+ Commercially available leads

Stelid II BJF25D steroid eluting atrial leads and Stelix II BRF25D steroid eluting atrial leads

The Stelid II BJF25D was evaluated in a 30-patient observational study. This lead is the same as the BTF25D/26D studied in the randomized control trial with the exception of the length, intended chamber of the heart, and J shape. The BRF25D was evaluated in a 32-patient observational study. This lead is the same as BR45D/46D studied in the randomized control trial, except that they use a 2 mm^2 vitreous carbon electrode instead of a 4 mm^2 electrode. The 2 mm^2 vitreous carbon electrode was also incorporated on the BTF25D/26D leads which were studied in the randomized control trial. For both Stelid II observational studies, the routine evaluation consisted of pre-implant screening, implant, and a follow-up at one month post implant. Table 3 summarizes the adverse events reported during these two studies. The study investigator determined that no deaths were device related.

Table 3: Adverse Events for Stelid II BJF25D and Stelid II BRF25D

	Stelid II BJF25D			Stelix II BRF25D		
Nature of event	Number of patients	Percent of patients	Number of events	Number of patients	Percent of patients	Number of events
Non-device related death	--	--	--	--	--	--
Loss of atrial capture	2	6.67 %	2	--	--	--
Axillary vein thrombosis	1	3.3 %	1	--	--	--
Pneumothorax	1	3.3 %	1	--	--	--
Dislodgement	--	--	--	1	3.1 %	1
VA crosstalk	--	--	--	1	3.1 %	1
Atrial fibrillation at implant	--	--	--	1	3.1 %	1
Serious, not related	--	--	--	2	6.3 %	2

IX. SUMMARY OF NON-CLINICAL STUDIES

Non-clinical testing of the Stelid II, Stelix, and Stelix II was conducted to ensure that the components and the finished device perform in accordance with their design specifications.

Stelid II non-clinical testing

The BTF25/26D, UTF25/26D, and BJF24/25D are very similar to each other. The UTF25/26D is a simpler version of the BTF25/26D with a single electrode, a single conductor, no inner silicone insulation, no welded parts and fewer glued joints. The

materials used in all 3 designs are the same: silicone insulation, MP35N conductor, stainless steel IS-1 connector tip, titanium IS-1 connector ring, vitreous carbon distal electrode, and platinum-iridium proximal electrode (bipolar models). The only difference between the two bipolar models is their shape.

Because the design and construction of the Stelid II family of leads is very similar from one model to another, qualification testing was performed primarily with the BTF2xD model and the results obtained were considered applicable to all Stelid II models. Where some aspect of lead design or construction was significantly different (for example J-shape versus straight), additional testing was conducted to qualify that aspect.

Stelix and Stelix II non-clinical testing
The BR45D/46D and the BRF25D/26D are very similar to each other. The materials and components used in the BR45/46D are the same as those used for the BRF25D/26D: silicone insulation, MP35N conductor, stainless steel IS-1 connector tip, titanium IS-1 connector ring, vitreous carbon distal electrode and platinum iridium proximal electrode.

Because the design and construction of the Stelix and Stelix II leads are nearly identical, qualification testing was performed primarily with the BR4xD model and the results obtained were considered applicable to the Stelix II models. Where the distal electrode surface area may have an impact on test results, additional testing was performed on Stelix II models to qualify this aspect.

In summary, all tests showed that the Stelid II, Stelix, and Stelix II leads function within specifications under normal operating conditions and when subjected to severe mechanical and electrical conditions.

The following standards were applied:

- pr EN 45502-2, Active Implantable Medical Devices (draft standard), Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (Pacemaker), September 1996.
- EN 50077: 1993, Low-profile connector implantable cardiac pacemakers (IS-1 standard), November 1993.

The nonclinical testing of the Stelid II, Stelix, and Stelix II included electronic and mechanical tests (including packaging and shipping), as described in the tables, below:

Table 4: Electronic and Mechanical Testing

Summary of Electronic and Mechanical Testing	Sample Size	Model No.	Test Results (Pass*/Fail)
Electrical Continuity			
Tests were conducted to determine resistance measurements of proximal and distal conductors.	3 3	BTF26D UTF26D	Pass
Leakage Current			
Samples were immersed for a minimum of ten days then rinsed, dried, and re-immersed for a minimum of an hour, after which the conductor resistance was measured. Following resistance measurements, leakage current was measured with voltage applied.	3 3 3	BTF25D BJF25D UTF26D	Pass
Tensile strength of Bonds			
Leads were evaluated for permanent elongation and visible damage following pull tests for the proximal bond, distal bond and composite lead.	3 3 3	BTF26D UTF26D BJF25D	Pass
Fluid ingress at the distal end			
Leads were tested for leaks at the distal end following 10-day immersion in Ringer's solution at 100 degrees C.	3 3 3	BTF26D UTF26D BJF25D	Pass
Corrosion resistance			
Testing consisted of immersion in Ringer's solution for a minimum of ten days followed by visual inspection under magnification.	3 3 3	BTF25D BJF26D UTF26D	Pass
Stylet performance			
Stylet performance was assessed by performing insertion and removal test. Electrical continuity and hermeticity after insertion were verified.	3 3	BTF26D UTF26D	Pass
Fatigue resistance			
Fatigue testing was performed after ten-day immersion in Ringer's solution. Passive fixation leads were tested at the straight portion of the lead, between ring and tip electrodes, between the ring electrode and lead body, and between the tip electrode and radio opaque ring. Active fixation leads were tested at the straight portion of the lead, between ring and tip electrodes, and between the ring electrode and lead body.	3 3	BTF26D UTF26D	Pass
Connector conformance			
The connector conformance was evaluated by verifying that the dimensions conform to the IS-1 standard and by measuring insertion and extraction forces.	3 3	BTF26D BTF25D	Pass
Anchoring sleeve operation			
Testing consisted of applying two ligatures to an anchoring sleeve positioned on a lead followed by gross lead, eletrical resistance, and dielectric strength tests.	3	leads + sleeves	Pass

* "Pass" denotes that the device meets established performance criteria and specifications, or is in conformance with the requirements of the reference standard.

Table 5: Steroid Elution

Summary of Steroid Testing	Sample Size	Model No.	Test Results (Pass*/Fail)
In-vitro steroid elution			
Unmounted steroid collars were immersed in physiologic saline and analyzed to determine the amount of steroid eluted over a 24 to 48-hour time period.	3	N/A	Pass
Steroid shelf life			
Samples were tested after one and three years of storage to verify that the amount of available steroid was still within specification after aged storage.	3 5	UTF45D UTF26D	Pass
Drug matrix/swelling			
Samples were visually inspected for proper position of the steroid collar prior to testing. The samples were then immersed for ten days after which they were visually inspected to verify that the gap between the steroid collar and the electrode remained.	3	BTF26D	Pass

*"Pass" denotes that the device meets established performance criteria

Table 6: Packaging and Shelf Life

Summary of Packaging and Shelf Life	Sample Size	Test Results (Pass*/Fail)
Packaging and shelf life testing was conducted on leads packaged and sterilized at least three years ago. The purpose of this testing was to demonstrate that lead sterility was preserved and that electrical and mechanical performance remained within specification. A fixed screw lead model sold in Europe (BS4xD), that has the same materials of construction as the Stelid II leads and is packaged and sterilized in exactly the same manner was used for this testing.	1 to 6	Pass

* "Pass" denotes that the device meets established performance criteria

Biocompatibility Evaluation

The tissue contacting materials used in the Stelid II lead Models BTF25D/26D are medical grade silicone, dexamethesone sodium phospate, and platinum/iridium alloy. The silicone and platinum-iridium alloy used in these leads are the same as those used in ELA's commercially available Models BT45/6 and BJ44/5 leads. The biocompatibility of the silicone and platinum-iridium was established in a commercially available device (K993448 April 10, 2000). DSP and Parylene-C are new materials used in the Stelid II lead models BBTF25D/26D. The biocompatibility test data for DSP is contained in Drug Master File No. 3693. Test data and literature included in the PMA support the biocompatibility of Parylene-C. The testing performed in support of the commercially available device and the

Sterilization Validation

Sterilization assessments were performed and validated that the leads can be effectively sterilized with a 100% ethylene oxide (EtO) sterilization process. The sterilization processes remain the same as those previously approved for the Stela lead family.

Shelf Life for PMA Devices

Expiration dating for this device has been established at 3 years from the date of sterilization.

X. CLINICAL STUDIES

Stelid II BTF25D/26D steroid eluting ventricular lead and Stelix BR45D/46D steroid eluting atrial lead

To evaluate the safety and effectiveness of the Stelid II steroid eluting ventricular lead and Stelix steroid eluting atrial lead, a prospective randomized controlled study was conducted at 30 sites. Safety and effectiveness results for patients receiving an implantable pacemaker with Stelid II steroid eluting ventricular leads and Stelix steroid eluting atrial leads were compared to those receiving commercially available non-steroidal leads.

Methods

Patients were implanted with either a Stelix BR45D/46D steroid eluting atrial lead and Stelid II BTF25D/26D steroid eluting ventricular lead or non-steroidal control leads. The randomization ratio was 3:1 (test: control).

Time frame: The study's routine evaluation consisted of pre-implant screening, implant, and scheduled follow-up visits at two weeks, one month, and three months. Investigators also documented unscheduled follow-up visits, explants, and patients lost to follow-up.

Primary effectiveness objectives: To demonstrate that pacing thresholds are lower than controls, pacing impedance is higher than controls and sensing thresholds are no lower than controls.

Endpoints:
Pacing thresholds at 0.49 ms pulse width measured at implant, two weeks, one month, and three months.
Sensing thresholds measured at implant, two weeks, one month, and three months.
Pacing impedance at 5 V measured at implant, two weeks, one month, and three months.
Pass/fail criteria:
Pacing thresholds: At least 30 % lower than non-steroidal control leads.
Sensing thresholds: Equivalent to non-steroidal control leads.
Pacing impedance: At least 30 % greater than non-steroidal control leads.

Primary safety objective: To demonstrate that the freedom from lead related complications with Stelid II and Stelix leads is no lower than controls.

Endpoint: Three-month complication-free rate.

Pass/fail criterion:
The three-month complication-free rate observed with steroid eluting leads must be equivalent to or better than that observed with non-steroidal control leads.

Patients studied

A total of 218 patients were implanted with Stelix BR45D/46D steroid eluting atrial leads and 77 patients received atrial non-steroidal control leads. Stelid II BTF25D/26D steroid eluting ventricular leads were implanted in 224 patients and 77 patients received ventricular non-steroidal control leads. Of these, 171 (56.6 %) patients were male with 124 (55.1 %) of them implanted with steroid eluting leads and 131 (43.4 %) patients were female with 101 (44.9 %) of them implanted with steroid eluting leads. Patient age ranged from 37 to 98 with a mean age of 75.7 years.

Primary indications for pacemaker implant were the following: may benefit from rate-adaptive pacing (3.3 %), symptomatic or paroxysmal second or third degree AV block (30.8 %), symptomatic bilateral bundle branch block (1.3 %), transient sinus node dysfunctions (32.5 %), brady-tachy syndrome (24.5 %), vaso-vagal syndromes or hypersensitive carotid sinus syndromes (1.3 %), and may benefit from maintenance of AV synchrony (6.3 %).

Effectiveness results: To compare the electrical performance of the Stelid II and Stelix leads, measurements were taken at implant and scheduled follow-ups at two weeks, one month, and three months. The primary effectiveness object stated that the Stelid II and Stelix leads were to have pacing thresholds lower than control leads, pacing impedances higher than control leads, and sensing thresholds no lower than control leads. The primary effectiveness object was not met. However, the data do demonstrate the new leads to be equivalent to the control leads. Because the data do not demonstrate better performance than the control, the leads cannot be called "high impedance" leads. The data presented at 2 weeks and one month demonstrate a 30% reduction in pacing threshold, supporting the effectiveness of the steroid tip in both the helix and tined versions. The helix version has only been tested for atrial use, therefore no claims will be made for use in the ventricle.

The tables below present the mean electrical measurements for steroid and control leads across all visits.

Table 7: Pacing threshold

Visit	Atrial Pacing threshold, Stelix	Atrial pacing threshold, control	Percentage difference [a]	Ventricular pacing threshold, Stelid II	Ventricular pacing threshold, control	Percentage difference [a]
Implant	0.55 V	0.72 V	24 %	0.4 V	0.38 V	-5 %
Two weeks	0.65 V	1.47 V	56 %	0.64 V	0.94 V	32 %
One month	0.61 V	1.46 V	58 %	0.68 V	0.93 V	26 %
Three months	0.63 V	1.25 V	49 %	0.71 V	0.83 V	15 %

[a] (Mean control – Mean steroid)/Mean control

Stelix steroid eluting atrial leads had significantly lower pacing thresholds than non-steroidal atrial control leads at two weeks, one month and three months post implant ($p<0.001$). Therefore, the primary effectiveness objective was met. The primary effectiveness object was not met at implant. However, pacing thresholds were equivalent for Stelix steroid eluting atrial leads and non-steroidal atrial control leads at implant ($p< 0.001$).

Stelid II steroid eluting ventricular leads did not have significantly lower pacing thresholds than non-steroidal ventricular control leads at implant and all follow-ups. Therefore, the primary effectiveness objective was not met.

Table 8: Pacing impedance

Visit	Atrial Pacing impedance, Stelix	Atrial pacing impedance, control	Percentage difference[b]	Ventricular pacing impedance, Stelid II	Ventricular pacing impedance, control	Percentage difference[b]
Implant	541 Ω	604 Ω	- 10 %	773 Ω	680 Ω	14 %
Two weeks	493 Ω	583 Ω	- 16 %	706 Ω	574 Ω	23 %
One month	496 Ω	607 Ω	- 18 %	743 Ω	653 Ω	14 %
Three months	499 Ω	636 Ω	- 22 %	751 Ω	685 Ω	10 %

[b] (Mean steroid- Mean Control)/Mean control

Stelix steroid eluting atrial leads did not have significantly higher pacing impedance compared to non-steroidal atrial control leads ($p>0.05$). Stelid II steroid eluting ventricular leads did not have significantly higher pacing impedance compared to non-steroidal ventricular control leads ($p>0.05$). Therefore, the primary effectiveness objectives were not met for both Stelix and Stelid II steroid eluting leads. However, pacing impedances for Stelix and Stelid II steroid eluting leads were equivalent to non steroidal control leads at implant and all follow-ups ($p<0.001$).

Table 9: Sensing threshold

Visit	Atrial sensing threshold, Stelix	Atrial sensing threshold, control	Percentage difference[c]	Ventricular sensing threshold, Stelid II	Ventricular sensing threshold, control	Percentage difference
Implant	2.52 mV	2.52 mV	0 %	9.15 mV	8.73 mV	5 %
Two weeks	2.78 mV	2.13 mV	31 %	9.43 mV	9.03 mV	4 %
One month	2.84 mV	2.19 mV	29 %	9.84 mV	9.65 mV	2 %
Three months	2.85 mV	2.42 mV	18 %	9.98 mV	9.93	1 %

[c] (Mean steroid- Mean control)/Mean control

Sensing thresholds were equivalent for Stelix steroid eluting atrial leads and non-steroidal control leads at implant and all follow-ups ($p < 0.001$). Stelid II steroid eluting

ventricular leads also provided sensing thresholds equivalent to non-steroidal control leads ($p < 0.001$). Therefore, the primary effectiveness objectives were met.

STELID II BJF25D STEROID ELUTING ATRIAL LEAD

The Stelid II BJF25D steroid eluting atrial lead uses the same silicone insulation, vitreous carbon distal electrode, platinum-iridium proximal electrode, steroid collar, and IS-1 bipolar connector as the Stelid II BTF25D steroid eluting ventricular lead. The only differences between the two leads are that the Stelid II BJF25D steroid eluting atrial lead is j-shaped and implanted in the atrium. The Stelid II BTF25D steroid eluting ventricular lead was evaluated in a prospective randomized controlled study. Because the Stelid II BJF25D steroid eluting atrial lead is similar to the Stelid II BTF25D steroid eluting ventricular lead, a 30-patient observational study was adequate to evaluate the safety and effectiveness of the Stelid II BJF25D steroid eluting atrial lead. Clinical data gathered on the Stelid II BJF25D steroid eluting atrial lead are applicable to the Stelid II BJF24D steroid eluting atrial lead because the only difference between the two leads is length.

Methods

Patients were implanted with a Stelid II BJF25D steroid eluting atrial lead.

Time frame: The study's routine evaluation consisted of pre-implant screening, implant, and a follow-up at one month post implant.

At implant and follow-up, pacing threshold (0.49 ms pulse width), pacing impedance at 5 V, p-wave amplitude (peak to peak), and sensing threshold were recorded.

Primary effectiveness objectives: To report pacing thresholds, pacing impedance, p-wave amplitude, and sensing thresholds for the BJF25D steroid eluting atrial lead.

Endpoints:
Pacing threshold at 0.49 ms pulse width measured at pre-discharge and one month.
P-wave amplitude (peak to peak) measured at pre-discharge and one month.

Primary safety objective: To report the incidence and nature of adverse events for the BJF25D steroid eluting atrial lead.

Endpoint: Adverse events

Patients studied

A total of 30 patients were implanted with Stelid II BJF25D steroid eluting atrial leads. Average patient age was 73 (± 9) years.

Primary indications for pacemaker implant were the following: AV block or bundle branch block (37 %), Sinus node dysfunction (53 %), other (7 %), or unknown (3 %).

Effectiveness results

To observe the electrical performance of the Stelid II BJF25D steroid eluting atrial lead, measurements were taken at implant and one month following implant.

The table below presents mean (± SD) electrical measurements for the BJF25D steroid eluting atrial lead.

	PRE-DISCHARGE		ONE MONTH	
PACING THRESHOLD	0.55 (± 0.28) V	(n= 28)	0.82 (± 0.74) V	(n= 29)
PACING IMPEDANCE	682 (± 82) Ω	(n= 29)	685 (± 83) Ω	(n= 30)
P-WAVE AMPLITUDE	1.8 (± 0.91) mV	(n= 26)	1.72 (± 0.83) mV	(n= 28)
SENSING THRESHOLD	3.1 (± 1.2) mV	(n= 19)	3.15 (± 0.85) mV	(n= 16)

Electrical measurements observed in this study were better than or comparable at one month to non-steroidal atrial control leads in the Stelid II/Stelix randomized, controlled study. Therefore, the primary effectiveness objectives were met.

STELIX II BRF25D STEROID ELUTING ATRIAL LEAD

The Stelix II BRF25D steroid eluting atrial lead uses the same silicone insulation, platinum-iridium proximal electrode, steroid collar, and IS-1 bipolar connector as the Stelix BR45D steroid eluting atrial lead. The only difference between the two leads is that the BRF25D steroid eluting atrial lead has a 2 mm^2 distal electrode, which has the same active surface area as the BTF25D steroid eluting ventricular leads. The Stelix BR45D steroid eluting atrial lead and Stelid II BTF25D steroid eluting ventricular lead were evaluated in a prospective randomized, controlled study. Because the Stelix II BRF25D steroid eluting atrial lead is similar to the Stelix BR45D steroid eluting atrial lead and Stelid II BTF25D steroid eluting ventricular lead, a 30-patient observational study was adequate to evaluate the safety and effectiveness of the Stelix II BRF25D steroid eluting atrial leads. Clinical data gathered on the Stelix II BRF25D steroid eluting atrial lead are applicable to the Stelix II BRF26D steroid eluting atrial lead because the only difference between the two leads is length.

Methods

Patients were implanted with Stelix II BRF25D steroid eluting atrial leads.

Time frame: The study's routine evaluation consisted of pre-implant screening, implant, and follow-up at one month post implant.

At implant and follow-up, pacing threshold (0.49 ms pulse width), pacing impedance at 5 V, and p-wave amplitude (peak to peak) measurements were recorded.

Primary effectiveness objectives: To report pacing thresholds, pacing impedance and p-wave amplitude for the Stelix II BRF25D steroid eluting atrial lead.

Endpoints:
Pacing threshold at 0.49 ms pulse width measured at pre-discharge and one month.
P-wave amplitude (peak to peak) measured at pre-discharge and one month.

Primary safety objective: To report the incidence and nature of adverse events with the Stelix II BRF25D steroid eluting atrial lead.

Endpoint: Adverse events

Patients studied

A total of 32 patients were implanted with Stelix II BRF25D steroid eluting atrial leads. Average patient age was 78 (± 9) years.

Primary indications for pacemaker implant were the following: AV block or bundle branch block (34 %), Sinus node dysfunction (40 %), both (19 %), or other (7 %).

Effectiveness results

To observe electrical performance of the Stelix II BRF25D steroid eluting atrial leads, measurements were taken at implant and one month following implant.

The table below presents mean (± SD) electrical measurements for the BRF25D atrial lead.

	PRE-DISCHARGE	ONE MONTH	PASS/FAIL CRITERIA
PACING THRESHOLD	0.59 (± 0.26) V (n= 30)	0.72 (± 0.33) V (n=30)	≤ 1.46 (± 0.66) V
PACING IMPEDANCE	572 (± 62) Ω (n= 29)	577 (± 44) Ω (n= 31)	≥ 607 (± 51) Ω
P-WAVE AMPLITUDE	2.29 (± 1.1) mV (n= 19)	2.0 (± 0.7) mV (n= 24)	--

Electrical measurements observed in this study were better than or comparable at one month to non-steroidal atrial control leads in the Stelid II/Stelix randomized, controlled study. Therefore, the primary effectiveness objective were met.

STELID II UTF25D AND UTF26D

The UTF25D/26D leads use the same insulation material and conductor coil material, and have the same number of filars, as ELA's marketed Stela UT46 lead (K000029). The only difference between the leads is that the UTF25D/26D leads have a reduced electrode surface area and a steroid-eluting collar. The electrode and steroid-eluting collar are the same as those on the BTF26D lead, for which the multicenter, prospective, randomized clinical study was conducted. Since all the features of these leads have been studied in the clinical studies, further data were not necessary to validate these leads.

XI. CONCLUSIONS DRAWN FROM THE STUDIES

The results of the clinical and non-clinical studies provide reasonable assurance of safety and effectiveness of the ELA Medical Stelid II, Stelix and Stelix II steroid eluting lead models when used as indicated in accordance with the directions for use.

XII. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for the review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CDRH DECISION

FDA issued an approval order on June 17, 2004. The conditions of Approval are those outlined in the attached Conditions of Approval for Cardiac Pacemakers and Programmers. In addition to the postapproval requirements in the enclosure, the postapproval reports must include the results of fatigue testing conducted out to 400 million cycles on all lead models within one month of test completion.

The sponsor's manufacturing facilities were inspected and determined to be in compliance with the Quality System Regulation (21 CFR part 820).

IX. APPROVAL SPECIFICATIONS

Directions for Use	See labeling
Hazards to Health from Use of the Device:	See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the Labeling
Post-approval Requirements, Restrictions:	See approval order.